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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
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ART UNIT	**PAPER NUMBER**
1648	12

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)	
Examiner	Group Art Unit	

—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication .
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

☒ Responsive to communication(s) filed on 6/5/02.

☐ This action is **FINAL.**

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 1 1; 453 O.G. 213.

Disposition of Claims

☐ Claim(s) 1-69 is/are pending in the application.

Of the above claim(s) 17-20, 23, 24, 28-41, 44 & 45 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) 1-16, 21, 22, 25-27, 42, 43, & 46-69 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 11 9(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 1 7.2(a)).

*Certified copies not received: _____.

Attachm nt(s)

☒ Information Disclosure Statement(s), PTO-1449, Pap r No(s). 5

☐ Interview Summary, PTO-413

☐ Notice of Reference(s) Cited, PTO-892

☐ Notice of Informal Patent Application, PTO-152

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Other _____

Office Action Summary

This Office Action is in response to the Election filed 6/5/02. Applicant elected, with traverse, Group II, claims 1-16, 21, 22, 25-27, 42, 43, and 46-69, directed towards SEQ ID NO: 2. Applicant's traversal is on the grounds that the claimed sequences are not from very different sources or effect different diseases, that there would not be a serious burden on the Examiner, the members of the Markush group are related by both structure and used to effect the same or similar diseases and Applicant does not believe that the Examiner provided sufficient reason to support an allegation that a serious burden would be placed on the Office to require the present restriction. Applicant further argues that the Markush claim such as 21 reciting the peptides has "only" 14 elements which are related by both structure and use, the invention generally related to the concept of inducing mucosal CTL response by contacting a mucosal tissue of a subject with a composition comprising a soluble antigen, more specifically, a number of distinct soluble peptides from a number of sources, and in particular, the peptide comprises a cluster peptide, and applicant believes these encompass a single invention. Applicant further asserts that the peptide of SEQ ID NOs:1-14 share a substantial structural feature disclosed necessary to the claimed utility that are composed of sub-regions. Applicant believes that the members of the Markush-type claims are sufficiently few in number or so

closely related that a search and examination of the generic claims drawn to the members of the claims can be made without serious burden on the Examiner.

The claimed antigens are not limited to the Markush-type claim, and, therefore, an immense number of possible antigens fall within the scope of the claims. The different peptides are argued to have a common structure which is persuasive in part. For example, SEQ ID NOs: 1-7 share a common carboxyl terminal: RIQ...IGK. This is not common to SEQ ID NOs 8-14. Further, this common segment is not novel and is well known in the art. Therefore, SEQ ID NOs: 1-7 do not have a special technical feature that defines them over the art. Applicant also argues that the common inventive concept is the induction of a protective CTL response by administering soluble antigen to a mucosal surface. This is known in the art and does not confer a special technical feature to the claims.

The requirement is still deemed proper and is therefore made FINAL.

This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 49 and 55 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 49, it is not clear what a rectal emulsion is. How is it distinguished from any other "emulsion"?

In claim 55, what is a base material?

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-16, 21, 22, 25-27, 42, and 43 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility.

While the specification does contain statements regarding the use of the invention as a vaccine, the specification fails to teach, nor does it describe such use. The difficulties inherent to

development of an HIV vaccine are well known. For the sake of clarity, some of those problems are be outlined here:

1) the extensive genomic diversity associated with the HIV retrovirus, due in large part to error prone reverse transcription of its single-stranded RNA genome,

2) the fact that the modes of viral transmission include virus-infected mononuclear cells, which pass the infecting virus to other cells in a covert form (cell to cell transmission), as well as via free virus transmission,

3) the existence of latent forms of the virus (i.e., beyond the blood-brain barrier),

5) the complexity and variation of the elaboration of the disease and,

6) the property of some portions of HIV proteins or peptides to actually cause immunosuppression or other detrimental consequences.

The existence of these obstacles prevents one of ordinary skill in the art from accepting any vaccine or immunization treatment or any therapeutic regimen on its face given the intense interest in developing HIV vaccines and the lack of success in doing so. In order to provide proof of utility with regard to drugs and their uses, either clinical or art accepted *in vivo* or *in vitro* data, or a combination of these can be used. However, the

data must be such as to convince one of ordinary skill in the art that the proposed utility is sufficiently established. See *in re Irons*, 340 F.2d 924, 144 USPQ 351 (CCPA 1965), *Ex parte Krepelka*, 231 USPQ 746 (PTO Bd. Pat. App & Inter. 1986) and *Ex parte Chwang*, 231 USPQ 751 (PTO Bd. Pat. App & Inter. 1986).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-16, 21, 22, 25-27, 42, and 43 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 46-48, 59, and 66 are rejected under 35 U.S.C. § 102(b) as being anticipated by Ahlers et al.(The J. of Imm., IDS ref. AH).

The preamble of the claims is not accorded significant patentable weight as it describes an intended use of the known antigen. Ahlers et al. teaches immunogenic peptide compositions comprising SEQ ID NO: 2 (PCLUS 1-18) which is a CTL epitope and is the V3 loop of gp120. See entire reference, most particularly page 5650, second column, under Results. The composition can be installed in the rectum as an enema. The antigen is administered with an adjuvant, see page 5649, under Immunizations. Thus, the instant invention is anticipated by Ahlers et al.

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103, the examiner

presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. § 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C. § 103(a).

Claims 46-69 are rejected under 35 U.S.C. § 103(a) as obvious over Ahlers et al. in view of the admissions of the specification.

The relevance of Ahlers et al. has been discussed above. It does not explicitly teach the numerous specific adjuvants, however, they are known in the art as exemplified in the specification. For example, see the last paragraph at the end of page 16 for teachings that various mucosal adjuvants are known in the art. Page 21, first full paragraph and the next paragraph, various rectal delivery formulations are known See also, the top of page 23. It would have been within the skill of the art of the ordinary artisan at the time the invention was made to modify the antigenic peptide disclosed by Ahlers et al. with known carriers, adjuvants, etc., with the expectation of optimizing its use as an immunogen. Therefore, the instant invention is obvious over Ahlers et al. in view of known vaccine components.

No claims are allowed.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989).

The Group 1600 Fax numbers are: (703) 308-4242 and (703) 305-3014.

Unofficial communications may be faxed to: (703) 308-4426.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Stucker whose telephone number is (703) 308-4237. The examiner can normally be reached Monday to Thursday from 7:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached on (703) 308-4027.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jeffrey Stucker

JEFFREY STUCKER
PRIMARY EXAMINER